K072331

page 1/2

510 (k) SUMMARY

Radiancy (Israel) Ltd.'s Radiancy's Mistral® Device

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

JAN - 7 2008

Manufacturer:	Radiancy (Israel) Ltd. 9 Gav Rave Street Industrial Park Yavne Israel Telephone: +972-8-9438010 Facsimile: +972-8-9438020
Contact Person:	Zvi Ladin, PhD. Principal Boston MedTech Advisors, Inc. 990 Washington Street Suite #204 Dedham, MA 02026 Telephone: (781) 407 0900 x104 Facsimile: (781) 407 0901 Email: zladin@bmtadvisors.com
Date Prepared:	August 15, 2007

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name:	Radiancy Mistral® Device
Common Name:	Pulsed Light System and Light Unit Assembly (LUA)
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21 C.F.R. § 878.4810)
Manufacturing Facility:	Radiancy (Israel) Ltd. 9 Gan Rave Street Industrial Park Yavne, Israel
Establishment Registration Number:	9616256
Owner/operator number:	9040071

Predicate Devices

Radiancy SkinStation System (K052442), General Project's MED FLASH II (K051508) and McCue's Energist Ultra VPL (K060234).

Intended Use / Indications for Use

The Radiancy's Mistral® Device is intended to provide phototherapeutic light and heat energy to the body and is generally indicated to treat dermatological conditions. The Mistral is specifically indicated for hair removal and treatment of vascular and pigmented lesions, mild to moderate inflammatory acne vulgaris which includes pustular acne, and mild to moderate psoriasis in patients with Fitzpatrick skin types I-VI.

Technological Characteristics

Radiancy's Mistral Device is a Light and Heat Energy (LHE®) based multi-application device intended for the phototherapeautic treatment of: Hair Removal (HR), Skin Photo Rejuvenation (SPR), Acne Clearance (AC) and Psoriasis Care (PC). Mistral consists of a console, footswitch and interchangeable handpieces. It uses the same technology and has the same indications as the previously cleared SkinStation System.

Substantial Equivalence

The Radiancy Mistral Device has the same intended use and indications for use, principles of operation and technological characteristics as the cleared Radiancy SkinStation. When used for hair removal, it has the same intended use, indications for use and is technologically similar to General Project's MED FLASH II and McCue's Ultra VPL devices. The slight differences between Mistral and its predicate devices do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2008

Radiancy (Israel) Ltd.
% Boston MedTech Advisors, Inc.
Zvi Ladin, Ph.D.
990 Washington Street, Suite 204
Dedham, Massachusetts 02026

Re: K072331
Trade/Device Name: Radiancy Mistral Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 8, 2007
Received: November 9, 2007

Dear Dr. Ladin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072331

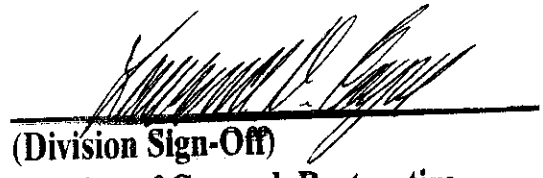
Device Name: Radiancy Mistral Device

Indications For Use: The Radiancy's Mistral Device is intended to provide phototherapeutic light and heat energy to the body and is generally indicated to treat dermatological conditions. The Mistral is specifically indicated for hair removal and treatment of vascular and pigmented lesions, mild to moderate inflammatory acne vulgaris which includes pustular acne, in patients with Fitzpatrick skin types I – VI, and mild to moderate psoriasis in patients with Fitzpatrick skin types I – VI.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072331